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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,359	07/23/2003	Daniel M. Deaton	900001-2115	8226
59945	7590	12/13/2006		
KOS PHARMACEUTICALS, INC. 1 CEDAR BROOK DRIVE CRANBURY, NJ 08512-3618			EXAMINER SINGH, JASVEER	
			ART UNIT 3772	PAPER NUMBER

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/625,359

Applicant(s)

DEATON ET AL.

Examiner

Jasveer Singh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 and 34-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 34-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 34-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 1 contains the limitation of a substantially air and moisture impermeable seal. The disclosure does not contain any description of this added feature to the seal as required by claim 1 as amended.

Further, independent claim 34 includes these same two limitations of claim 1 and thus the disclosure does not contain a description of these limitations in applicant's amended claims.

Claims 2-15 and claims 35-54 are rejected since the two groups depend on claim 1 and claim 34 respectively.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor (6,029,659) in view of Jewett (US 5,544,647).

As to claims 1-4, 6, and 8, O'Connor discloses an apparatus for dispensing medication comprising at least one canister 11 containing the medication to be dispensed, the canister 11 being movable in a first and a second direction. O'Connor continues to disclose a mouthpiece 12 providing a point of dispensation for the medication from the canister 11 to a user when the canister is moved in a first direction. In addition, O'Connor discloses a switch means 50 for completing an electrical circuit when the canister 11 moves in a first direction and opening the electrical circuit when the canister 11 moves in a second direction, wherein the switch means 50 is oriented to enable operational connectivity with the canister or canister discharge (see Figure 7). O'Connor includes a counter module 40 for performing a count upon the closure of the electrical circuit and displaying a dispensation history (41) of the medication in the canister 11. O'Connor discloses a seal 718 isolating the counter module 40

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from the mouthpiece and the canister to prevent contamination as shown in Figure 7.

O'Connor does not expressly disclose the switch means being contacted by a ferrule portion of the canister in a direction substantially non-axial to the first direction.

However, Jewett teaches a switch (42) contacted by a ferrule portion of canister (16) in a direction substantially non-axial to the first direction. Figure 1 of Jewett shows the ferrule portion of the canister (16), which is located in canister (16)'s bottom left corner, and how this ferrule region contacts the switch (42) at an angle with respect to the linear axis of the canister (16). Jewett teaches that "an internal or external microswitch 42 is closed by the downward motion of the canister 16. The microswitch closure triggers the microelectronic means to subtract "one" from any visual indicia count shown ... This visual confirmation of count also lets the patient know that there is no battery failure and adequate medication remains for a signaled number of remaining doses" (column 6, lines 61-68, column 7, lines 1-5).

Therefore, it would have been obvious, to a person having ordinary skill in the art at the time of the invention, to modify the device of O'Connor such that it would include the switch activation means of Jewett, as such a modification would result in a patient being able to visually confirm the count of the medication dose and also alerts a user of potential battery failure and an advance notice of remaining doses within in the canister.

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Also, O'Connor does not explicitly disclose the seal (718), isolating the counter module from the mouthpiece and the canister to prevent contamination, to be substantially air and moisture impermeable. However, it is inherent that the seal would be substantially air and moisture impermeable, since air and moisture would be mediums that could possibly contain contaminants, and O'Connor discloses that the seal (718) prevents contamination.

As for claims 2-4 and 6, O'Connor as modified by Jewett teach the dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61 – O'Connor). In addition, O'Connor teaches the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

As to claim 5, it would have been obvious to a person having ordinary skill in the art at the time of the invention to allow this device to be capable of varying the period of time for a dosage in order for the device to be reused with different medicines of varying dosage requirements.

As to claims 7 and 9, O'Connor as modified by Jewett teach the display portion 41 of the counter module 40 is on the back of the mouthpiece as shown in Figure 6. However, placing the display portion on the front of the mouthpiece or on the side of the mouthpiece are both equivalents of placing the display portion on the back of the mouthpiece. Accordingly, the examiner considers this to be an obvious matter of design choice and as such does not patentably

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distinguish these claims over the prior art. examiner considers the selection of such to be mere obvious matter of design choice and as such does not patently distinguish these claims over the prior art.

Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'connor in view of Jewett (US 5,544,647) and further in view of Rand et al. (US 6431168). O'Connor as modified by Jewett teach everything except the switch means including an electrically conductive contact imbedded in the seal. However, Rand et al. teach a similar apparatus for dispensing medication that includes a switch means 44 with an electrically conductive contact 46/47 imbedded in the seal 40. Therefore, it would have been obvious to a person ordinary skill in the art at the time of the invention to modify the device of O'connor/Jewett to replace this switch means with the switch means taught by Rand et al. in order to increase the reaction speed of the switch from movement of the canister as well as improve the accuracy of having a switch react via conductive contact versus force of contact.

As for claims 11 and 12, O'connor as modified by Jewett teach a portion of the counter module 40 disposed external to the mouthpiece 12 as shown in Figure 5. It is considered a mechanical equivalent to place a portion of the counter module within the mouthpiece.

In addition, Rand et al. device teaches the counter module as being partially disposed within the mouthpiece especially if the mouthpiece includes portion 3 until 20. Accordingly, the examiner considers the selection of such to be mere

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obvious matter of design choice and as such does not patently distinguish the claims over the prior art.

As to claims 13-15, O'Connor as modified by Jewett teaches everything except the seal including a ramp that acts upon the switch. However, Rand et al. teaches the seal passing above switch 44 including a ramp 47/46 that act upon the switch means 44 when the canister 2 is moved in the first direction as shown in Figures 8 and 9. In addition, Rand et al. teaches the switch means 44 as being mounted on a circuit board 49 (column 8, lines 17-22) and is acted upon by a ferrule portion 11 of the canister 2, the switch means 44 being isolated from the canister by a second seal 5 (column 4, lines 12-20). Rand et al. also teaches the seal 40 being made of conductive material (sections 47/46). Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify O'Connor/Jewett with the switch means system of Rand et al. in order to improve the reaction time of the circuit.

Claims 34-37 and 39, 40, 42, 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor and Jewett in further view of Rand et al.

O'Connor discloses an apparatus for dispensing medication comprising at least one canister 11 containing the medication to be dispensed, the canister 11 being movable in a first and a second direction. O'Connor discloses a switch means 50 for completing an electrical circuit when the canister 11 moves in a first direction and opening the electrical circuit when the canister 11 moves in a second direction. O'Connor includes a counter module 40 for performing a count upon the closure of the electrical circuit and displaying a dispensation history (41)



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of the medication in the canister 11. O'Connor discloses a ramp seal 718 isolating the counter module 40 from the mouthpiece and the canister to prevent contamination as shown in Figure 7.

However, Jewett teaches switch (42) contacted by a ferrule portion of canister (16) in a direction substantially non-axial to the first direction. Figure 1 of Jewett shows the ferrule portion of the canister (16), which is located in canister (16)'s bottom left corner, and how this ferrule region contacts the switch (42) at an angle with respect to the linear axis of the canister (16). Jewett teaches that "an internal or external microswitch 42 is closed by the downward motion of the canister 16. The microswitch closure triggers the microelectronic means to subtract "one" from any visual indicia count shown ... This visual confirmation of count also lets the patient know that there is no battery failure and adequate medication remains for a signaled number of remaining doses" (column 6, lines 61-68, column 7, lines 1-5).

Therefore, it would have been obvious, to a person having ordinary skill in the art at the time of the invention, to modify the device of O'Connor such that it would include the switch activation means of Jewett, as such a modification would result in a patient being able to visually confirm the count of the medication dose and also alerts a user of potential battery failure and an advance notice of remaining doses within in the canister.

Also, O'Connor does not explicitly disclose the seal (718), isolating the counter module from the mouthpiece and the canister to prevent contamination, to be substantially air and moisture impermeable. However, it is inherent that the

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seal would be substantially air and moisture impermeable, since air and moisture would be mediums that could possibly contain contaminants, and O'Connor discloses that the seal (718) prevents contamination.

As for claims 35-37 and 39, O'Connor as modified by Jewett teach a dispensation history that includes the number of doses of medication remaining in the canister (column 3, lines 58-61). In addition, O'Connor as modified by Jewett teach the history including the number of doses taken of a dosage sequence the number of doses taken over a period of time (column 5, lines 19-24 and column 4, lines 52-55). O'Connor continues to disclose the dispensation history including time since the last dispensation of the medication (column 5, lines 46-55).

As to claim 38, it would have been obvious to one having ordinary skill in the art at the time of the invention to allow this device to be capable of varying the period of time for a dosage in order for the device to be used with different medicines of varying dosage requirements.

As to claims 40, 41, and 42, O'Connor has disclosed the display portion 41 of the counter module 40 is on the back of the mouthpiece as shown in Figure 6. However, placing the display portion on the front of the mouthpiece or on the side of the mouthpiece are both equivalents of placing the display portion on the back of the mouthpiece. Accordingly, the examiner considers the selection of such to be mere obvious matter of design choice and as such does not patentably distinguish these claims over the prior art.

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As to claim 43, O'Connor/Jewett teach everything except the switch means including an electrically conductive contact imbedded in the seal. However, Rand et al. teach a similar apparatus for dispensing medication that includes a switch means 44 with an electrically conductive contact 46/47 imbedded in the seal 40. Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device of O'Connor/Jewett to replace this switch means with the switch means taught by Rand et al. in order to increase the reaction speed of the switch from movement of the canister as well as improve the accuracy of having a switch react via conductive contact versus force of contact.

Claims 44-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor. O'Connor discloses a ferrule portion of the canister 11 acting upon a ramp seal 51. O'Connor continues to teach the counter 40 and ramp seal 51 as being formed in a common component. In addition, O'Connor discloses a sump for a nozzle of the canister wherein the counter, ramp seal and sump are formed as a common component as shown in Figure 5. The device's common component of O'Connor is capable of being injection moldable. In addition, this device's common component is capable of being adaptable to canister holders for a variety of canister shapes and sizes. O'Connor's common component is adaptable to canister holders for a variety of canister shapes and sizes. In addition, it is considered well known in the art that this device is adaptable to canister holders for a variety of canister shapes and sizes for many different users. This device also includes the components including a canister

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holder, a canister, a mouthpiece, and a counter, wherein the counter is adaptable for use with a canister holder, canister, and a mouthpiece capable of being made of a variety of sizes and shapes. Therefore, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments filed 4/6/2006, with respect to the rejection(s) of claim(s) 1-54 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, and in view of applicant's amendments to the claims pending, a new ground(s) of rejection was made (see rejections above).

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is

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filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

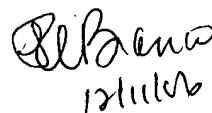
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jasveer Singh whose telephone number is (571) 272-5508. The examiner can normally be reached on M-F (9am - 6pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jasveer Singh

Handwritten signature of Jasveer Singh in cursive script.